

M4•9

**Self-Contained
Steam Sterilizer**

MIDMARK

Installation & Operation Guide



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Owner's Product Identification

(information that you will need to provide for servicing - key information is highlighted)

Date of Purchase

Serial Number

Name of Owner / Facility / Department

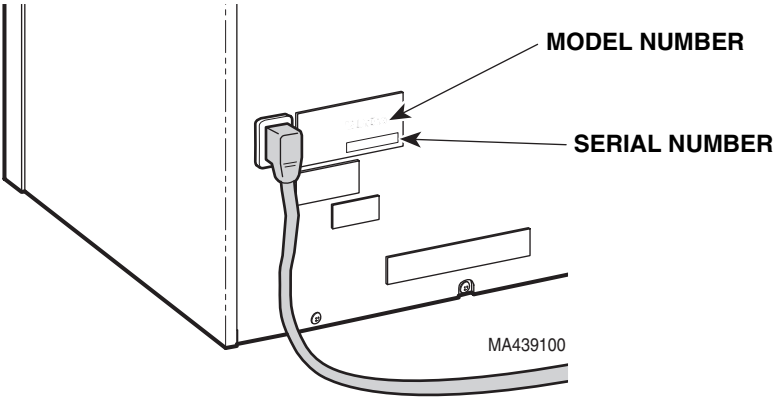
Model Number

Name of Authorized Midmark Dealer

Telephone # of Authorized Midmark Dealer

Address of Authorized Midmark Dealer

MODEL AND SERIAL NUMBER LOCATION



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IMPORTANT INFORMATION

Scope and Purpose of This Manual

This manual provides complete instructions for the installation, operation, and normal care of the M 4•9 EasyClave™ Steam Sterilizer. It is intended that this manual be used by all personnel operating the sterilizer or performing operator level maintenance. No repair information is included in this manual as no repairs are authorized at the operator level.

Intended Use of Product

The M 4•9 EasyClave™ is to be used in medical and dental offices, hospitals, clinics, nursing homes, laboratories, and other facilities to sterilize heat and moisture stable reusable items (including dental handpieces) that are compatible with steam sterilization at 270°F (132°C). Refer to Loading Trays and Standard Cycle Parameters later in this manual for detailed information.

Safety Instructions

The primary concern of Midmark is that this equipment is operated and maintained with the safety of the patient and staff in mind. To assure safer and more reliable operation:

- Read and understand this manual before attempting to install or operate the sterilizer.
- Assure that appropriate personnel are informed on the contents of this manual; this is the responsibility of the purchaser.
- Assure that this manual is located near the sterilizer, or if possible, permanently affixed to the sterilizer.

Explanation of Safety Symbols and Notes

Important Information



DANGER

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury. The **DANGER** symbol is limited to the most extreme situations.



WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.



CAUTION

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.



EQUIPMENT ALERT

Indicates an imminently or potentially hazardous situation which, if not avoided, will or may result in serious, moderate, or minor equipment damage.

NOTE

Amplifies an operating procedure, practice, or condition.

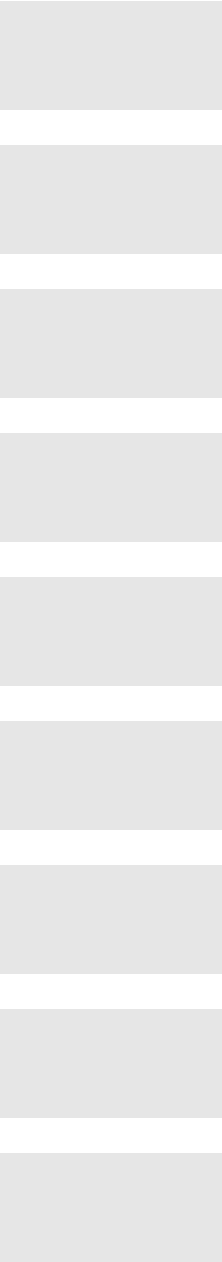
Transportation and Storage Conditions



EQUIPMENT ALERT

The water must be drained from the unit’s reservoir before transporting or storing at 32°F (0°C) or below.

- Storage Temperature Range: -40°F to 158°F (-40°C to +70°C)
- Relative Humidity 10% to 90% (non-condensing)



INSTALLATION

Location Requirements For Sterilizer

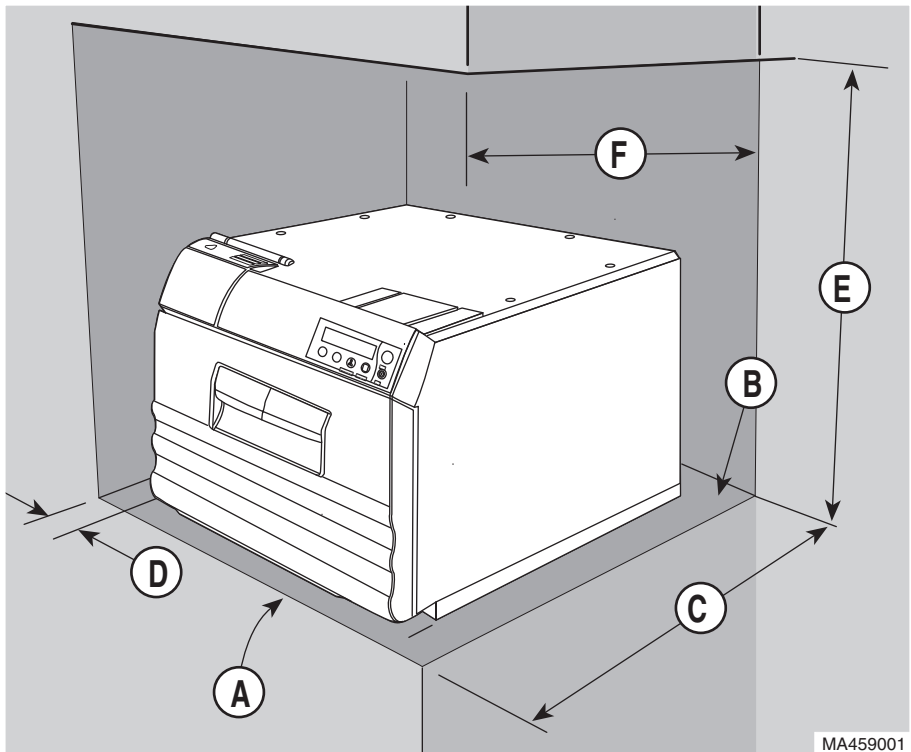
Installation



DANGER

Do not operate this sterilizer in areas where flammable anesthetics are used or stored. An explosion could occur, causing personal injury.

Adherence to the following recommendations for location of the sterilizer will contribute to optimum performance of the unit:



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Support Surface (A) - Sterilizer must be placed on a level surface to ensure that the chamber will fill correctly. Improper water level in the chamber could cause a sterilizer malfunction.

Support Surface Material (B) - Place sterilizer on a Formica, stainless steel, stone, or other water resistant material.

Support Surface Depth (C) - Support surface should be at least 19 in. (48.3 cm) deep. Allow at least 2 in. (5.1 cm) clearance behind the sterilizer for air circulation.

Distance To Side Wall (D) - If the sterilizer is located next to side walls, there should be no less than 2 in. (5.1 cm) clearance between the side of the sterilizer and the wall.

Distance Above Sterilizer (E) - If the sterilizer is to be located beneath wall cabinets or shelves, the underside of the cabinets or shelves should be at least 17.5 in. (44.45 cm) above the support surface to allow access to the printer for changing the printer paper roll.

Overhang (F) - If the sterilizer is to be located beneath an overhang, the underside of the overhang should project no further than 15 in. (38.1 cm) over the rear of the sterilizer.

Location On Support Surface - The front of the sterilizer should be located near the front of the support surface so water can be easily drained from the tube into a container.

Neighboring Materials and Equipment - If the sterilizer will be operated in continuous cycles, locate the sterilizer where steam will not damage materials or equipment in the surrounding area.

Operating Environment Conditions



EQUIPMENT ALERT

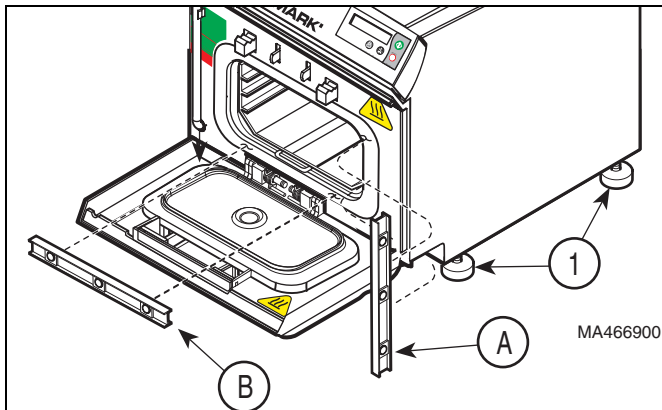
The unit should be allowed to reach room temperature before operating. Failure to do so could result in damage to the unit.

- Operating Environment
Temperature Range:- 68°F to 104°F (20°C to 40°C)
- Normal Operating Altitude: Below 6560 ft. (2000 m) above sea level.
- Device approved for Indoor Use Only.
- Device to be operated in a relatively dust free environment. An excessive relative humidity environment should be avoided. Less than 90% (non condensing) is recommended. (Pollution Degree 2, in accordance to IEC664)
- Device should be connected to a power source with over-voltage limits less than 1500 volts from mains to ground. (Installation Category II in accordance to IEC 664)

Installation

Leveling the Sterilizer

1. Check the front to back level (A) and adjust leveling feet (1) if necessary..
2. Check side to side level (B) and adjust leveling feet (1) if necessary.
3. Recheck level in both directions (A,B) until unit is stable and level in both directions



Re-Location Requirements For Sterilizer

1. Disconnect power cord from the electrical outlet and allow sterilizer to cool.
2. Drain water from reservoir or take care not to tip the sterilizer, which will allow water to spill from reservoir.

Electrical Requirements



WARNING

Use 207 - 253 VAC, 50/60 HZ alternating current only for 230 VAC rated models and 104 - 127 VAC, 50/60 HZ alternating current only for 115 VAC rated models. Failure to do so could result in electrical shock to personnel and will result in damage to sterilizer.

Do not use this sterilizer in an explosive or oxygen-enriched atmosphere. Failure to do so could result in serious personal injury or death.



EQUIPMENT ALERT

The unit should be allowed to reach room temperature before operating. Failure to do so could result in damage to the unit.

NOTE

Grounding reliability can only be achieved if this unit is connected to a matching three-pronged, grounded, isolated, correctly polarized receptacle.

The three-pronged grounding plug on the sterilizer power cord must be plugged into a matching three-pronged, grounded, isolated, correctly polarized receptacle. The electrical rating for the 230 VAC unit is 230 VAC, 50/60 Hz, 6.5 amps; this sterilizer must be connected to a dedicated branch circuit rated for 220 VAC, 50/60 Hz, 10 amps. The electrical rating for the 115 VAC unit is 115 VAC, 50/60 Hz, 12 amps; this sterilizer must be connected to a dedicated branch circuit rated for 115 VAC, 50/60 Hz, 15 amps. Check the serial number label on the back panel of the sterilizer to verify the voltage rating for the unit.

DESCRIPTION

Operational Features

The M4•9 EasyClave™ sterilizer . . .

- displays messages and uses audible “beeps” to indicate the status of a cycle. Also displays error messages and uses audible “beeps” to indicate malfunctions.
- automatically initializes the on-board computer and runs a self-diagnostic test when the unit is plugged in.
- preheats the chamber of the sterilizer for 90 minutes after each sterilization cycle to allow for “quick start” cycles.

Installation

Description

Description

- begins a sterilization program cycle when either the **UNWRAPPED** or **WRAPPED** program is selected, the door is closed and fully latched, and the **START** button is pressed.
- automatically fills the chamber with water to the correct level once the **START** button is pressed.
- begins the cycle time countdown only after the proper pressure and temperature have been reached (the cycle time remaining is displayed).
- automatically exhausts steam from the chamber and opens the door slightly to facilitate drying upon completion of the sterilization phase.
- automatically begins a drying phase which runs from a minimum of 20 minutes to a maximum of 40 minutes, depending on initial chamber temperature (running back to back cycles will lower the dry time toward the 20 minute minimum). However, the drying phase may be stopped at any time by pressing the **STOP** button.
- signals the operator that the drying phase and therefore the sterilization program cycle is complete by sounding audible “beeps”. At this time, the sterilizer may be unloaded, reloaded, and restarted if additional sterilization programs are desired.
- prints a permanent record of actual exposure times and temperatures for each sterilization cycle (if unit has optional printer).
- signals the operator every 40 cycles for weekly maintenance and every 160 cycles for monthly maintenance.

Mechanical Features

The M4•9 EasyClave™ sterilizer . . .

- has a tray rack which can hold three trays **or** an optional pouch rack that fits a standard tray. The tray rack can be removed for periodic cleaning of the chamber and tray rack.
- has an optional printer which provides a permanent record of actual exposure times and temperatures.
- has an easily replaceable door seal which can be replaced by the operator in seconds.

Safety Features

The M4•9 EasyClave™ sterilizer . . .

- has a **door interlock** which prevents the operator from opening the door when the chamber is under pressure.
- has a **dry cycle door stop** which prevents the door from opening fully if there is a slight residual pressure in the chamber when the door handle is operated. The door stop also retains the door in a partially open position

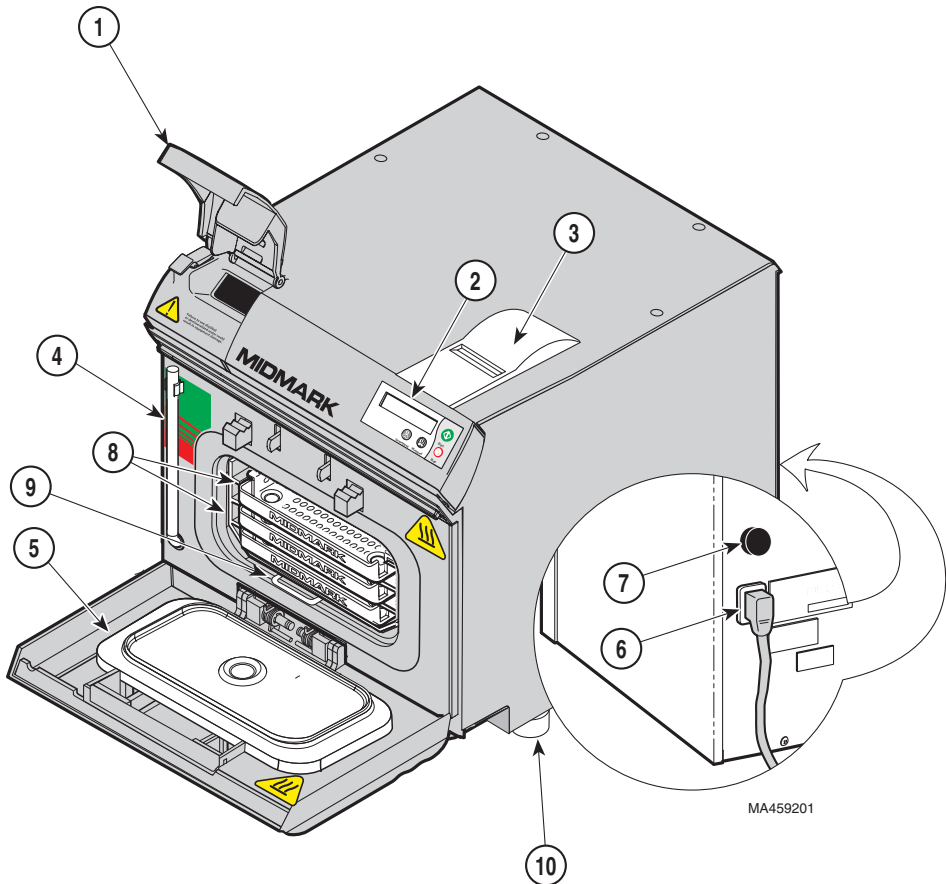
during the drying cycle.

- has a **door latched switch** which prevents operation until the door is completely closed and latched. An audible “beep” will sound and the message “Door Not Latched, Latch Door” will be displayed if the door is not fully latched.
- **monitors chamber temperature** during a cycle to prevent an overheat condition. If chamber temperature exceeds its preset limit, power to the heaters is cut off and the cycle is aborted.
- has a **pressure relief valve** which opens to provide backup protection to reduce chamber pressure in the event that the chamber steam pressure exceeds the allowable limit. Released steam is directed out of the bottom of the unit’s cabinet.
- has a **fault detection circuit** which monitors all functions of the sterilizer during a cycle. If a fault occurs during a cycle, the sterilizer monitoring circuitry will stop the cycle, sound an audible signal, and display the appropriate error message.
- displays the message “**Items not sterile**” if a sterilization cycle is interrupted by power loss, by the operator, or by a unit malfunction.

Description

COMPONENTS OVERVIEW

The illustration below shows the location of the sterilizer's major components and the chart below provides their descriptive name.

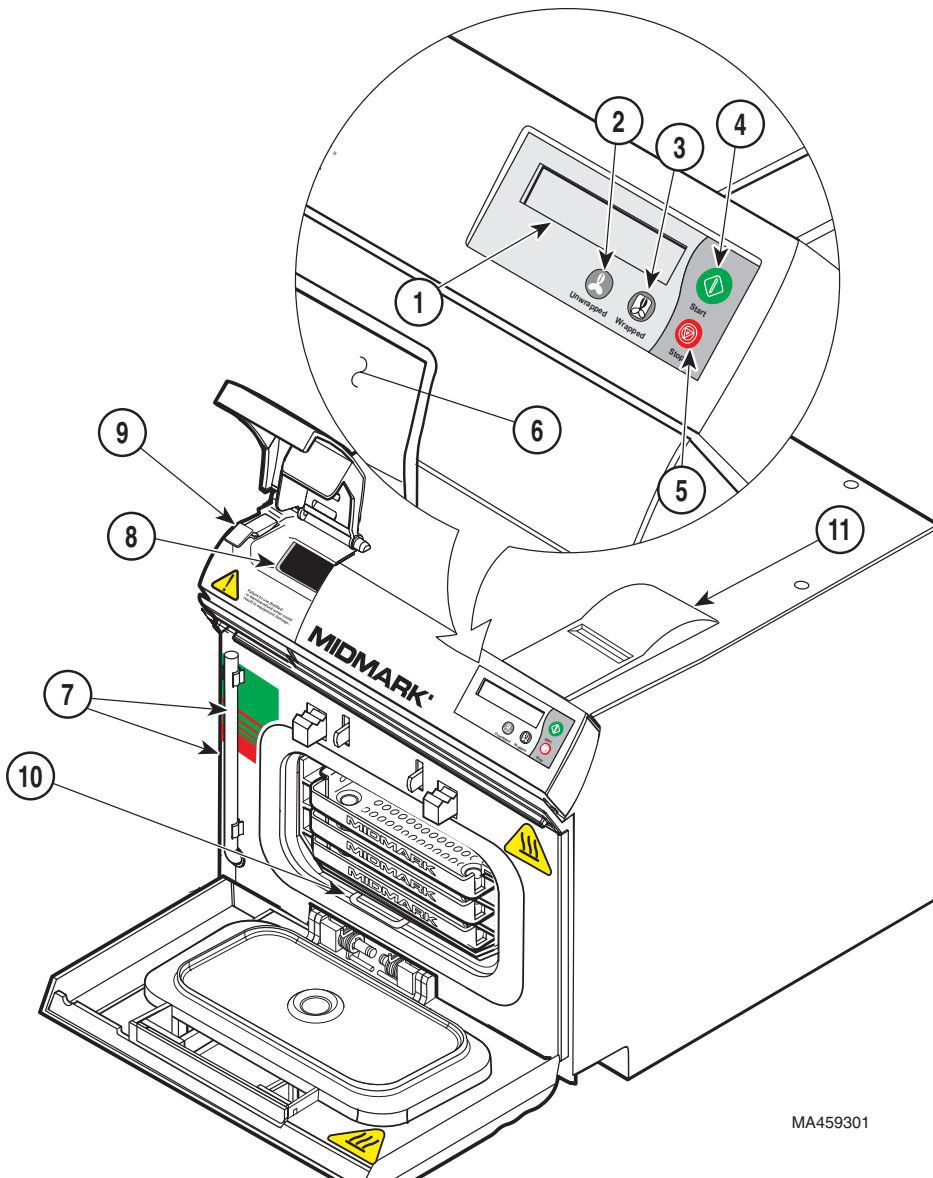


DESCRIPTION OF COMPONENTS

1. Water Fill Cover	6. Power Cord Receptacle
2. Display / Control Pad	7. Fuse
3. Printer (Optional)	8. Trays and Tray Rack
4. Water Level Indicator / Reservoir Drain Tube	9. Bail
5. Door Gasket	10. Leveling Feet

CONTROLS & INDICATORS

The following illustrations show the location of the sterilizer's controls and indicators and the chart on the following page describes their function.



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**Components
Overview**

**Controls &
Indicators**

Controls & Indicators

Ref.	Control	Function
1	Display	indicates cycle selected and the cycle temperature and exposure time for the selected cycle. During the cycle, the display shows messages describing the status of the cycle. When the cycle time enters the sterilization mode, remaining cycle time is displayed as well as the temperature and pressure. The display also shows the error message if a malfunction occurs. Refer to the Message Guide for a detailed explanation of each message.
2	UNWRAPPED button	when pressed, selects the program cycle designed to process unwrapped instruments including dental handpieces at 270°F (132°C) for 3:30 minutes with a 20 to 40 minute drying cycle following the sterilization phase (length of dry cycle depends on chamber temperature at start of cycle).
3	WRAPPED button	when pressed, selects the program cycle designed to process wrapped instruments including dental handpieces at 270°F (132°C) for 9 minutes with a 20 to 40 minute drying cycle following the sterilization phase (length of dry cycle depends on chamber temperature at start of cycle).
4	START button	when pressed, initiates the program cycle that has been selected.
5	STOP button	when pressed, terminates the program cycle currently in progress.
6	Door Handle	used to open or latch the door. The door handle is raised to unlatch the door and lowered to latch the door.
7	Water Level Indicator / Reservoir Drain Tube	indicates the water level in the reservoir. Also, the tube may be detached from its clips and used to drain the reservoir quickly and easily into a suitable container.
8	Fill opening	allows distilled or demineralized water to be poured into reservoir from the front of unit.
9	Pressure Relief Valve Test Lever	allows operator to check the pressure relief valve easily (see Perform Pressure Relief Valve Check under Monthly maintenance later in this manual).
10	Bail Handle	used to pull the bail partially out of the chamber to allow hot trays to be removed more easily.
11	Printer (Optional)	The printer (optional equipment) can be used to provide a permanent record of the time, temperature, and pressure during a cycle. Refer to the Printer section later in this manual for detailed information on printer installation and operation.

OPERATION



DANGER

Do not use this sterilizer in an explosive or oxygen-rich atmosphere, or where flammable anesthetics are stored. To do so could result in an explosion or fire.

If the sterilizer malfunctions, immediately unplug sterilizer. If the sterilizer continues to malfunction, call for service; do not attempt to repair the sterilizer yourself.



EQUIPMENT ALERT

For optimal sterilizer performance, allow the sterilizer to reach room temperature before operating.

Also, Do not use toweling or packaging which may contain chlorine bleach residue. Doing so could result in trays and/or chamber rusting or discoloring. In extreme cases, the life of the chamber may be significantly shortened.

Recommended Steam Sterilization Monitoring Program

Physical monitors (temperature and pressure measuring devices) can help detect sterilizer malfunctions. The sterilizer control system aborts the cycle and prints a message in the display if physical conditions go outside established limits. The Printer Accessory should be used to create a record of each load's actual cycle time, temperature, and pressure.

NOTE

Process monitors must be rated for use with Gravity Displacement Steam Sterilizers.

Process monitors (biological and chemical indicators) indicate if conditions in the sterilizing chamber were adequate to achieve sterilization. Process monitors cannot establish that a processed item is actually sterile. If a process monitor indicates a sterilization failure, items in that load are considered non-sterile. Improper packaging, improper loading, and sterilizer malfunction can cause sterilization failures. Determine the cause for all sterilization failures and take steps to remedy the cause before processing additional items in the sterilizer. Follow the process monitor manufacturer's instructions for proper selection, storage, use, and interpretation for their devices.

Follow appropriate agency (state dental or medical board) sterilization monitoring guidelines for your office. Information can also be obtained from CDC, AAMI, OSAP, and ADA on monitoring programs and other sterilization issues.

**Controls &
Indicators**

Operation

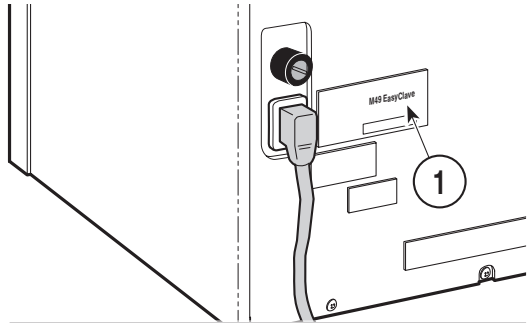
Sterilizer Preparation Before Operation



EQUIPMENT ALERT

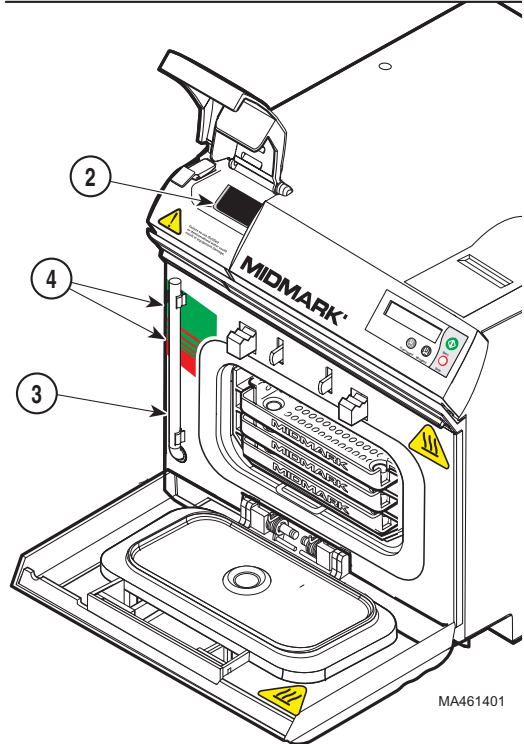
Check the serial number label (1) on the back panel of the sterilizer to verify the voltage rating for the unit. Failure to connect the sterilizer to an appropriate power supply could result in damage to the unit.

1. Locate the sterilizer and plug in its power cord in accordance with the Installation instructions contained earlier in this manual. The LCD display will show “**Initializing System**” and then “**Total Cycles XXXX Ver X.XX**”.



EQUIPMENT ALERT

Use only distilled or demineralized water. The chlorine found in normal tap water has a severe corrosive effect on the stainless steel chamber. Failure to use distilled or demineralized water may cause serious deterioration and premature failure of the stainless steel chamber which could result in serious injury or death.



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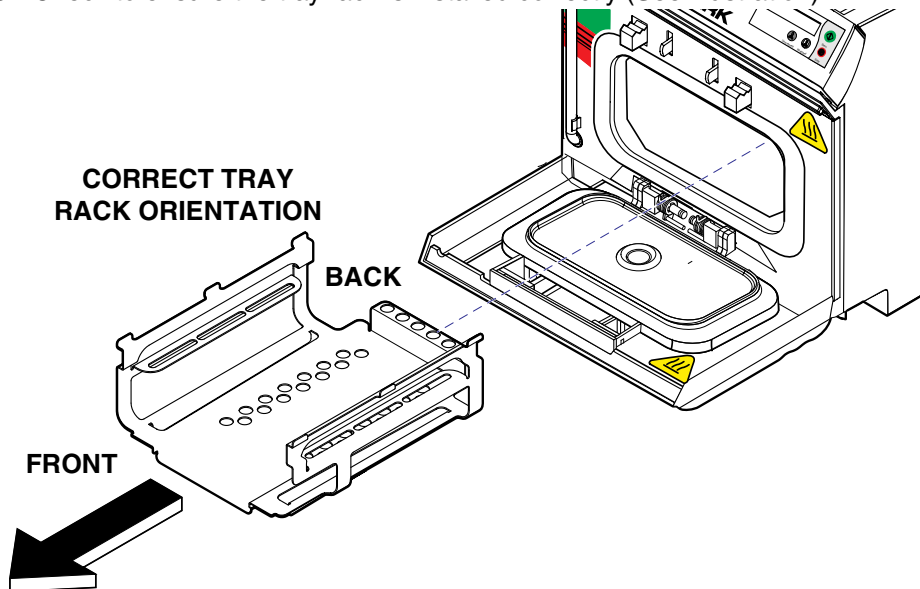
2. Open the water fill cover and pour distilled or demineralized water into the fill opening (2) until the water level found in the Water Level Indicator Tube (3) is at the top of the fill level label (4).



EQUIPMENT ALERT

Check to make sure the tray rack is installed correctly. If tray rack is installed backwards, the unit will malfunction, resulting in a failed cycle and could result in damage to the unit.

3. Check to ensure the tray rack is installed correctly (See Illustration).



Cleaning Instruments



DANGER

Clean and dry instruments before putting them into the sterilizer. Incomplete and improper cleaning of instruments will impede sterilization and will result in non-sterile instruments which could lead to personal injury or death.

- Follow item manufacturer's and OSHA recommendations for handling and cleaning items.
- As soon as possible after use, remove all material or residue accumulated during use.
- Rinse items thoroughly to complete removal of material and residue.
- Dry items completely.

Guidelines For Loading the M 4•9

- Refer to manufacturers' recommendations for loading their items.
- Refer to cassette manufacturers' recommendations for using their cassettes.
- Pouch or wrap items to preserve sterility after processing. Use only protective coverings designed and recommended for steam sterilization at 270°F (132°C).
- Do not wrap items too tightly. Sterilization will be compromised if an item is excessively wrapped.
- Do not overload the chamber. Adequate space is required around items in trays for steam circulation and drying. Failure to allow adequate space will compromise sterilization and drying.
- Place all containers so that the opening allows steam to enter, and air and condensate to drain from the container.
- Sterilize jointed items in an open position.
- Use only M 4•9 trays. Using other trays could restrict air and steam flow to items.
- Place unwrapped items on a towel or absorbent paper.
- Pouches may overlap, but handpieces and instruments must be single height loaded (not piled or stacked), to permit proper steam flow and penetration to the items.
- Maximum Load per Tray: 3 dental handpieces or 30 instruments
- Maximum Chamber Load: 3 trays (9 handpieces or 90 instruments).



Operation



WARNING

Do not use this sterilizer in an explosive or oxygen-rich atmosphere, or where flammable anesthetics are stored. To do so could result in an explosion or fire.

Do not use this sterilizer for sterilizing volatile substances or for any purpose other than its intended design. Burns and toxic or explosive conditions could result.

Do not operate sterilizer without tray rack in place or installed backwards. Doing so will result in sterilizer overheating and will result in an unsuccessful sterilization cycle.

Clean and dry instruments before putting them into the sterilizer. Incomplete and improper cleaning of instruments will impede sterilization and will result in non-sterile instruments which could lead to personal injury or death.

If the sterilizer malfunctions, immediately unplug sterilizer. If the sterilizer continues to malfunction, call for service; do not attempt to repair the sterilizer yourself.

Do not force door handle at any time. Chamber pressure may cause door to open with extreme force. If the door handle does not move freely, allow unit to cool and depressurize for 40 minutes before opening door. Failure to adhere could result in serious personal injury or death.

NOTE

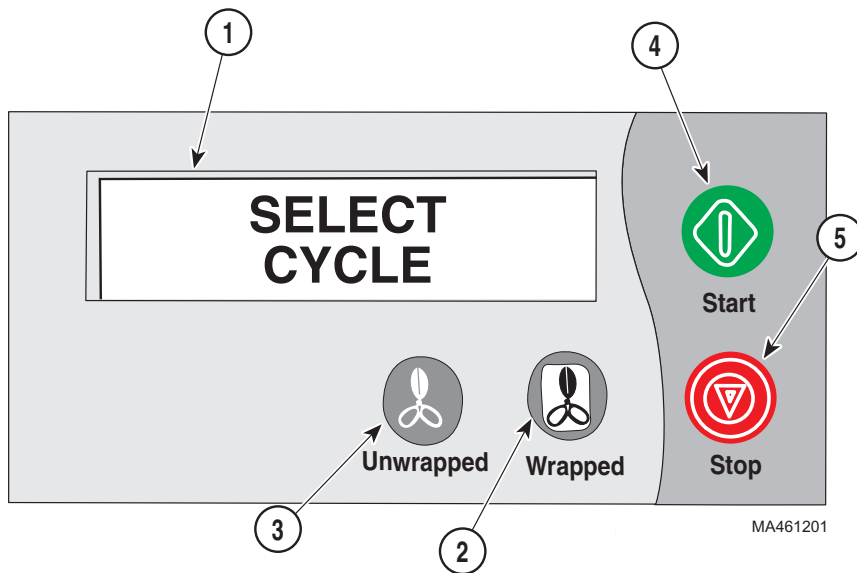
Use sterility monitors with each sterilization load. If a sterilizing cycle is terminated prematurely, reprocess the instruments to ensure the sterility of the load.

Refer to the following steps for a detailed description of the program operating procedures:

NOTE

The chamber will automatically stay pre-heated for a period of 90 minutes from the completion of the last cycle run.

1. The LCD display (1) will show “**Select Cycle**” if the chamber *is not* pre-



heated (it has been more than 90 minutes since the end of the last cycle) or “**Select Cycle Chamber Preheated**” if the chamber *is* pre-heated (it has been less than 90 minutes since the end of the last cycle).

2. Close and latch the door; the sterilizer will not operate unless the door is closed and latched properly.



EQUIPMENT ALERT

Processing goods using an incorrect sterilization program could result in non-sterile goods and may damage instruments. Consult the instrument manufacturer for specific sterilization instructions.

3. Select either the **WRAPPED** (2) or **UNWRAPPED** (3) sterilization cycle program in accordance with the Standard Cycle Parameters table (see section later in this manual).
 - The LCD display (1) shows the selected program’s parameters. If **WRAPPED** cycle is selected, “**Wrapped 270°F (132°C) 9 Minutes**” is displayed. If **UNWRAPPED** cycle is selected, “**Unwrapped 270°F (132°C) 3:30 Minutes**” is displayed.
 - If an incorrect program selection is made, select the correct program

cycle by pressing the correct program cycle button (2 or 3).



WARNING

The **STOP** button may be pressed at any time to stop or interrupt a cycle. However, the goods being sterilized must not be considered sterile if the cycle is stopped any time before the dry cycle.

4. Press the **START** button (4).

NOTE

On units using the metric display, **XXX°F** will display as **XXX°C** and **XX.X PSI** will display as **XXX KPA**

- The sterilizer sounds a beep for two seconds to indicate that the sterilization cycle has started.
- The chamber automatically fills to the correct level with water while the LCD display shows “**Filling Chamber**”. When chamber is full, the LCD display shows “**Chamber Is Full**”.
- The heat up portion of the cycle begins and the LCD display shows “**Heating Wrapped XXX°F XX.X PSI**” or “**Heating Unwrapped XXX°F XX.X PSI**”. The LCD display is continuously updated with current temperature and pressure in chamber.
- When the correct temperature and pressure is reached, the sterilizer begins the sterilizing portion of the cycle; the LCD displays shows “**Sterilizing MM:SS XXX°F XX.X PSI**”. On the LCD display, the time remaining in the sterilizing portion of the cycle is counted down while the current temperature and pressure in the chamber is continuously updated.
- When 10 seconds remain in the sterilizing portion of the cycle, the LCD display shows “****Ready To Vent** MM:SS XXX°F XX.X PSI**”.
- When the time remaining in the sterilizing portion of the cycle reaches 0:00, the LCD display shows “**Venting Chamber XXX°F XX.X PSI**”. The LCD display is continuously updated with current temperature and pressure in chamber. The vent valve is opened and the sterilizer vents the steam and water in the chamber back into the reservoir or optional external condensing tank.



WARNING

Keep clear when the door is ready to open. Do not attempt to open door until steam dissipates. Failure to do so could result in severe burns from steam being released.

- When the pressure in the chamber is reduced to zero, the LCD display shows “****Door To Open** XXX°F XX.X PSI**” and the door is actuated

Operation

open to the dry mode (partially open) position.

NOTE

The sterility of wrapped or packed instruments cannot be ensured unless the wrapped or packed instruments are allowed to dry.

- After the door opens, the LCD display shows “**Items Sterilized Dry Cycle MM:SS**” and starts the drying portion of the cycle. On the LCD display, the time remaining in the drying portion of the cycle is counted down. If desired, the drying portion of the cycle can be aborted by pressing the **STOP** button (5).
- When the time remaining in the drying portion of the cycle reaches 0:00, the LCD display shows “**Dry Cycle Complete**” and sounds a 10 second beep.



CAUTION

The processed load and metal inner surfaces will be hot at the completion of the sterilizing or drying phase. Avoid contact with hot surfaces. Failure to do so could result in serious burns.

5. Remove the processed load from the chamber (See Unloading Hot Trays and Cassettes later in this manual).
6. The sterilizer will automatically go into a pre-heat mode that will keep the chamber pre-heated for a period of 90 minutes.
7. The sterilizer may now be restarted for another cycle.

Unloading Hot Trays and Cassettes (Using Tray/Cassette Tool)

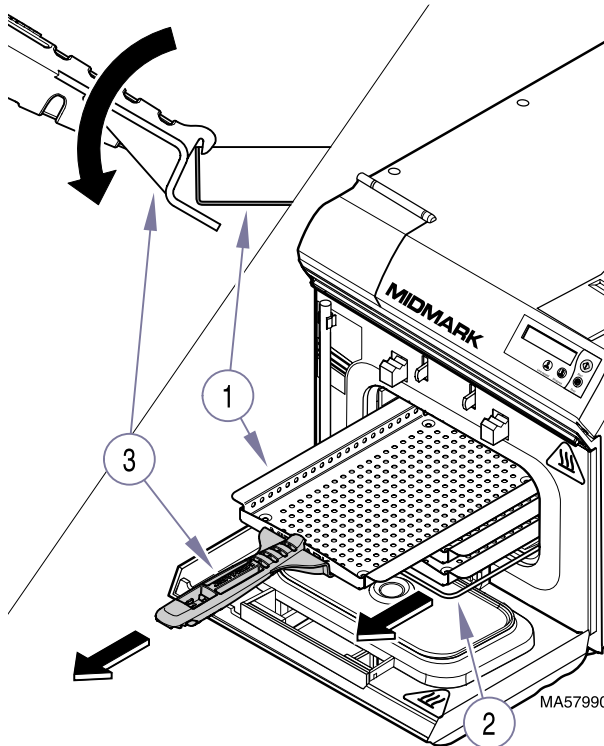


CAUTION

Only use this tool with Midmark manufactured trays. Use care when removing or transporting the trays, or cassettes as they may be hot. Hold the tray level and slightly elevated to prevent it from shifting and becoming dislodged. Failure to comply may result in personal injury due to burns.

To remove a tray (1) from the chamber, pull out bail (2) to access the trays. Then, hook the top tab of the tool (3) to the top center of the tray lip.

Rotate tool downward until bottom forks are completely beneath tray. Check to ensure the tray is being held securely and then remove the tray from the chamber.



CAUTION

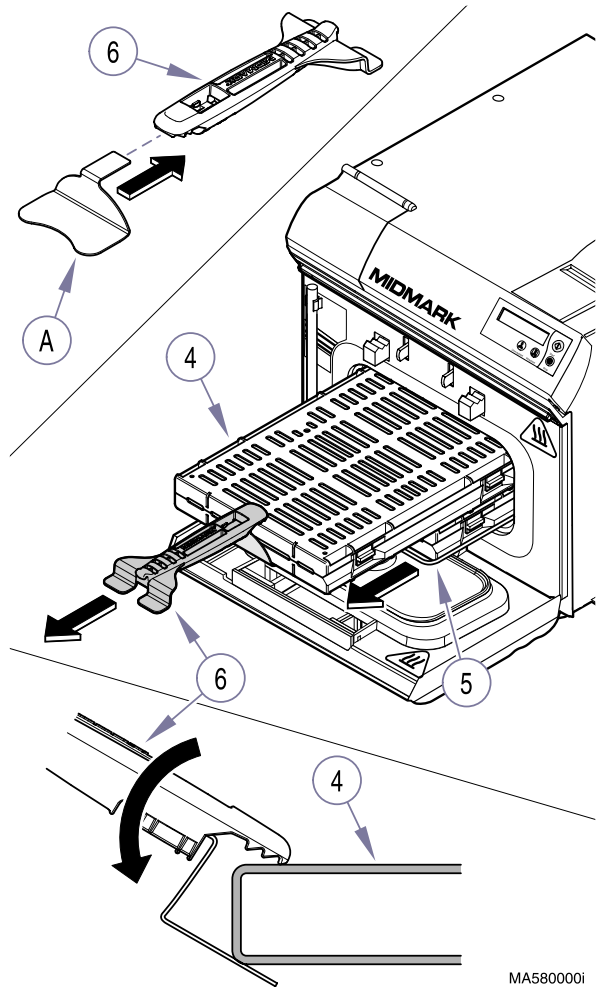
When removing the cassette, hold the cassette tool so the end of the cassette is slightly elevated and use care to prevent it from sliding off the cassette tool.

NOTE

The cassette tool is capable of handling cassettes up to 1-1/2in. (3.8 cm) thick using the cassette plate built into the handle.

To remove a cassette (4) from the chamber, pull out bail (5) to access the cassettes. Insert cassette-plate (A) (larger plate) into end of the tool (6).

Hook top, saw-toothed tab of tool (6) to the top center of the cassette (4) while rotating tool downward until bottom plate is completely beneath the cassette. Check to ensure the cassette is being held securely and then remove the cassette from the chamber.



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Operation

Standard Cycle Parameters

The following table lists the standard cycle parameters for the UNWRAPPED and WRAPPED cycles.

Standard Cycle Parameters

PROGRAM	TEMP / PRES-SURE/TIME (minimums)	ITEMS TO BE STERILIZED (Always consult the item manufacturer's recommendations for sterilization.)
 Unwrapped	270°F (132°C) / 27.1 psi (186 kPa) for 3:30 minutes	Instruments loose on a tray. Dental hand-pieces. Open glass or metal canisters. Tubing not used in surgical procedures. Loose items manufacturers recommend for exposure at 270°F (132°C). The sterility of unwrapped items is compromised on exposure to a non-sterile environment.

Standard Cycle Parameters - Continued

PROGRAM	TEMP / PRES-SURE/TIME (min-ims)	ITEMS TO BE STERILIZED <i>(Always consult the item manufacturer's recomen-dations for sterilization.)</i>
 Wrapped	270°F (132°C) / 27.1 psi (186 kPa) for 9 minutes	Loosely wrapped or pouched instruments or dental handpieces. Multiple layers of instru-ments separated by fabric. Wrapped trays of loose instruments. Tubing not used in surgical procedures. Wrapped items manu-facturers recommend for exposure at 270°F (132°C).

List of Authorized Accessories

Listed below are the accessories which are authorized for use with this steriliz-er:

<u>Accessory Name</u>	<u>Order Number</u>
• Speedclean, 1 bottle	002-0396-00
• Speedclean, 1 case (12 bottles)	002-0396-01
• Printer Refill Kit	002-0371-00
• General Instrument Pouch Rack	9A258001
• Printer	9A259001
• External Condensing Tank	9A260001
• Tray / Cassette Tool	9A307001

OPERATOR MAINTENANCE

It is the responsibility of the user to establish a periodic maintenance procedure to assure correct operation of the equipment and reliable sterilization of the loads. Contact your local Midmark distributor or service representative to develop a program for planned maintenance.

Daily

- 1. Clean External Surfaces - Wipe with a soft dry cloth and wash occasionally with a damp cloth and mild soap or detergent.

Operation

Operator Maintenance

Weekly



EQUIPMENT ALERT

Do not use abrasive or bleaching agents in the chamber (i.e. steel wool, scouring powder, bleach, etc.). Also, never use a wire brush. If these materials are used, possible damage to the metal surfaces of the chamber and other components could result.

1. Clean Chamber and Trays - The sterilizing chamber and instrument trays should be cleaned weekly. First, drain the water from the reservoir. A drain tube is located on the front of the unit for draining. Wash the inside of the chamber and the trays with mild soap or Speed-Clean and distilled or demineralized water. Refill the reservoir with distilled or demineralized water.



WARNING

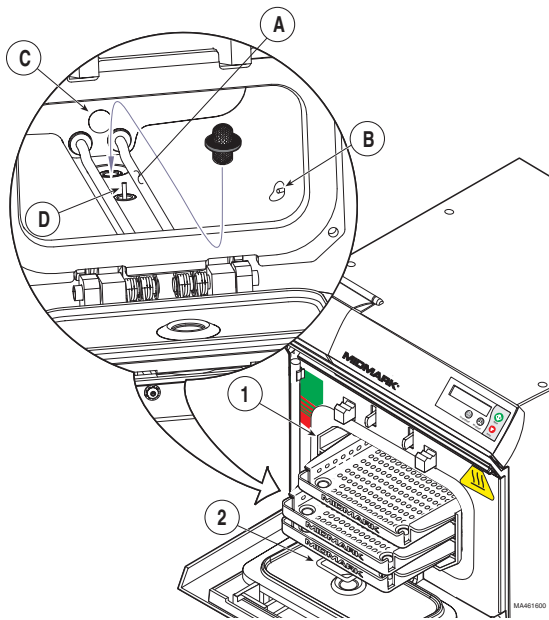
Make sure that the unit is cool when cleaning the door gasket and any mating surfaces. Failure to do so could result in serious burns to hands.

2. Clean Sterilizer Door Gasket - Clean door gasket sealing lip and mating surface with a damp cloth. Examine gasket for possible damage that could prevent a good seal.

Monthly

1. Clean Chamber and Plumbing - To help clean the chamber and plumbing of dirt and harmful deposits:
 - (a) Add one ounce of Speed Clean Sterilizer Cleaner to a cool chamber.
 - (b) Run one 9 minute (**WRAPPED**) cycle, stopping cycle when drying portion of cycle is reached. **Do not process instruments while cleaning the sterilizer.**
 - (c) After the cleaning cycle vents, drain the reservoir, refill the reservoir with clean distilled or demineralized water and run one 3 1/2 minute (**UNWRAPPED**) cycle to rinse any remaining Speed Clean Sterilizer Cleaner out of the system.
 - (d) After the rinsing cycle is finished, drain the reservoir and allow the sterilizer to cool (the **STOP** button should be pressed to abort the Dry Cycle). Preheat will continue to cycle on and off for 90 minutes unless unit is unplugged.

- (e) After the sterilizer has cooled sufficiently, remove the trays and then the tray rack (1) from the chamber by pulling out on bail handle (2). With a damp cloth, wipe out the inside of the chamber, being careful not to damage the heating element (A), steam temperature probe (B), level sensor probe (C), or the lower ([dry] sensor probe (D). Also, wipe off the trays and tray rack.



- (f) Re-install the tray rack.

- (g) Refill the reservoir with clean distilled or demineralized water.

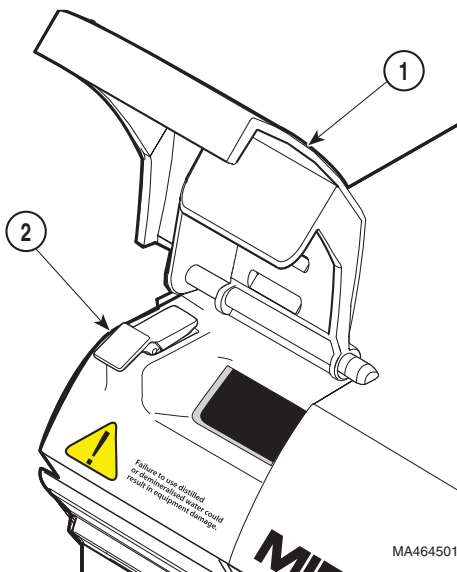
2. Perform Pressure Relief Valve Check - The pressure relief valve must be checked each month to be sure that the relief valve is functioning properly:

- (a) Open the water fill cover (1).
- (b) **START** an **UNWRAPPED CYCLE**.



WARNING

During the pressure relief valve check, steam will be vented from under the sterilizer. To keep from being burned, place a steam barrier (a rolled up towel) around the bottom of the sterilizer.



- (c) When the “heat up” portion of the cycle reaches 25 to 26 PSI (display should read **HEATING - UNWRAPPED XXX°F 25.5 PSI**), pull upward on pressure relief valve test lever (2) for approximately three seconds; steam should discharge freely from beneath the rear of the unit.

NOTE

If the pressure relief valve does not close completely when the test lever is released, pull the test lever again and release it quickly so the valve snaps back into position. Do this until the valve seats properly.

- (d) Release the test lever (2). When the test lever is released, the valve should seat, stopping the release of steam.
- (e) Press the **STOP** button to abort the cycle and prevent the unit from overheating.
- (f) If excessive force is required to open pressure relief valve or pressure relief valve will not reseat properly, the pressure relief valve must be replaced (See Calling For Service later in this manual).
- (g) Close the water fill cover (1).

Non-Scheduled Maintenance

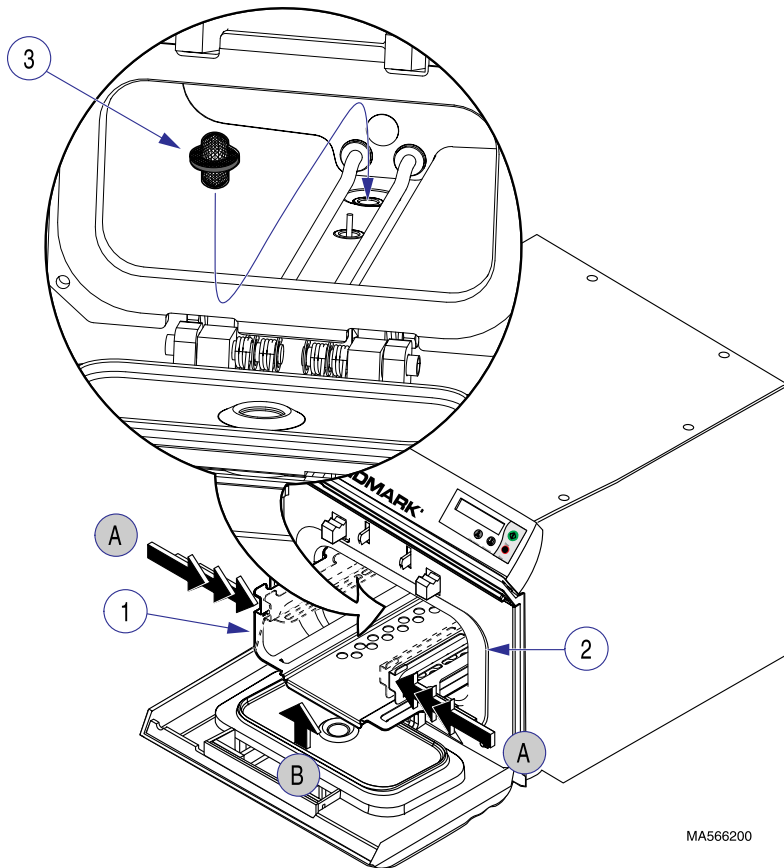
1. Cleaning Fill / Vent Filter Screen - This screen is intended to prevent dirt from causing valve failures. The screen should be cleaned if fill or vent times become too long:
 - (a) Unplug the power cord from the outlet receptacle.
 - (b) Open door and remove all trays.
 - (c) While pressing in on both sides (A) of tray rack (1), lift front edge (B) of tray rack upward slightly and then pull tray rack from chamber (2).
 - (d) Grasp the filter (3) and gently pull upwards while twisting slightly (a pair of pliers may be used if filter is stuck). The filter may be cleaned with mild soap and distilled or demineralized water. A small stiff bristled brush or ultrasonic cleaner may be helpful to remove foreign objects from the filter surface. Rinse the filter with distilled or demineralized water.



EQUIPMENT ALERT

Do not operate the sterilizer without the filter in place. Doing so could result in the sterilizer malfunctioning.

- (e) Re-install the filter (3) by inserting the filter into the hole in the chamber bottom and pressing downwards while twisting slightly.



MA566200



EQUIPMENT ALERT

Make sure the tray rack is installed correctly. If tray rack is installed backwards, the unit will malfunction, resulting in a failed cycle and could result in damage to the unit.

- (f) While pressing in on both sides (A) of tray rack (1), slide tray rack back into chamber (2), making sure tray rack is pushed in as far as it will go.
- (g) Plug unit power cord into outlet receptacle.

Operator
Maintenance

2. Cleaning Air Valve Filter Screen - This screen is intended to prevent dirt from causing air valve and temperature sensor failures. The screen should be cleaned when filter becomes dirty:

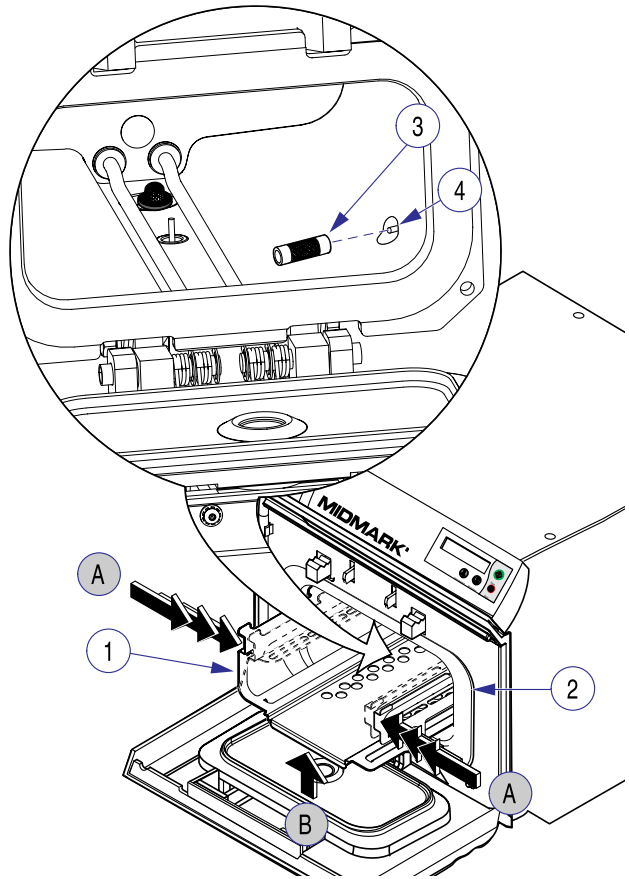
(a) Unplug the power cord from the outlet receptacle. Then, open door and remove trays.

(b) While pressing in on both sides (A) of tray rack (1), lift front edge (B) of tray rack upward slightly and then pull tray rack from chamber (2).

(c) Using a pointed instrument, pull filter screen (3) out of temp sensor cavity (4).

(d) The filter screen (3) may be cleaned with mild soap and distilled or demineralized water. A small stiff bristled brush or ultrasonic cleaner may be helpful to remove foreign objects from the filter surface. Rinse the filter with distilled or demineralized water.

(e) Push filter screen (1) into temp sensor cavity (A) as far as it will go.



**Operator
Maintenance**



EQUIPMENT ALERT

Make sure the tray rack is installed correctly. If tray rack is installed backwards, the unit will malfunction, resulting in a failed cycle and could result in damage to the unit.

(f) While pressing in on both sides (A) of tray rack (1), slide tray rack back into chamber (2), making sure tray rack is pushed in as far as it will go.

(g) Plug unit power cord into outlet receptacle.

Troubleshooting Guide

Use the following table to assist in correcting minor problems with the sterilizer.

TroubleShooting Guide

<i>Problem</i>	<i>Possible Cause</i>	<i>Solution</i>
<i>Steam is escaping from the pressure relief valve</i>	<i>pressure relief valve is not properly seated.</i>	<i>reseal the pressure relief valve (see Perform Pressure Relief Valve Check under Monthly maintenance).</i>
<i>Sterilization failure evidence from process monitor (chemical indicator, biological indicator, etc.)</i>	<i>sterilization conditions were not present at the location of the indicator.</i>	<i>reload the sterilizer in accordance with Guidelines For Loading the M 4•9. If problem recurs, unplug unit power cord and contact an authorized service representative (see Calling For Service).</i>
	<i>indicator is out-of-date, is inappropriate for sterilization cycle, or has otherwise malfunctioned.</i>	<i>use an indicator, appropriate for the load and cycle selected, that has been stored properly. Contact the indicator manufacturer for additional information on proper selection, use, storage, and potential misapplication or malfunction.</i>
<i>Door gasket leaks</i>	<i>door gasket is damaged or dirty.</i>	<i>allow sterilizer to cool; then clean or replace door gasket (see Clean Door Gasket under Weekly maintenance).</i>
<i>Items are not dry at the end of the drying portion of cycle.</i>	<i>sterilizer is improperly loaded.</i>	<i>reload the sterilizer in accordance with Guidelines For Loading the M 4•9. If problem recurs, unplug unit power cord and contact an authorized service representative (see Calling For Service).</i>
	<i>filter screen clogged.</i>	<i>allow sterilizer to cool and then clean or replace filter screen (see Cleaning Filter Screen).</i>
<i>Printer not printing</i>	<i>Printer cable is not connected properly.</i>	<i>Ensure that printer cable is connected to printer and PC board properly.</i>
	<i>Software malfunction.</i>	<i>Unplug sterilizer power cord, wait 15 seconds, and then plug sterilizer power cord back in.</i>
	<i>Printer is out of paper.</i>	<i>Insert a new paper roll (see Inserting the Paper Roll under Printer Installation and Operation).</i>

**Operator
Maintenance**

TroubleShooting Guide - Continued

Problem	Possible Cause	Solution
	Cartridge Ribbon is dried out or needs to be replaced.	Hold the switch in the ON / FEED position for three seconds. If this doesn't correct the problem, replace the cartridge ribbon (see Installing a New Cartridge Ribbon under Printer Installation and Operation in this manual).

Message Guide



CAUTION

The table below list all possible messages, possible causes for those messages, and then describes what may be done by the operator to correct the problem. If an error occurs more than once, do not continue to use the sterilizer. Unplug the unit and call an authorized service representative (see Calling For Service later in this manual).

Also, if an error message contains the phrase “**Items Not Sterile**”, the items in the sterilizer **shall not** be considered sterile; they **must** be run through a successful sterilization cycle.

Use the following table to determine the meaning of a message and assist in correcting minor problems with the sterilizer. Follow the instructions shown in the display when the error occurred.

Message Guide

Message	Possible Cause	Solution
Informational Messages		
INITIALIZING SYSTEM	Unit power cord was just plugged in - standard informational message.	normal operation will occur after a 4 second pause.
TOTAL CYCLES XXXX VERSION YYYY	Unit power cord was just plugged in - standard informational message.	normal operation will occur after this message.
PERFORM WEEKLY MAINTENANCE	This message is displayed every 40 cycles to prompt the operator to perform the weekly maintenance described in this manual.	Perform weekly maintenance. The message will automatically clear after the next cycle is completed.

Message Guide - Continued

Message	Possible Cause	Solution
PERFORM MONTHLY MAINTENANCE	<i>This message is displayed every 160 cycles to prompt the operator to perform the monthly maintenance described in this manual.</i>	<i>Perform monthly maintenance. The message will automatically clear after the next cycle is completed.</i>
TEMP REG WARNING CYCLE RESTARTED	<i>This message can occur when a heavy load (possibly a textile load) is being sterilized. A heavy load can result in excessive air in chamber, allowing temperature in chamber to exceed its low or high range limit. When this happens, the sterilization cycle is aborted, the chamber vents, and a new cycle automatically restarts.</i>	<i>Lighten any loads which cause this warning message to display (usually heavy textile loads). If warning message appears often, even when sterilizer is not overloaded, contact an authorized service representative (see Calling For Service later in this manual).</i>
Error Messages		
C010: POWER UP MODE SYSTEM PWR LOSS	<i>Unit had loss of power during cycle.</i>	<i>Push STOP button to restart.</i>
C060: POWER UP MODE SYSTEM HARDWARE	—	<i>Unplug unit power cord for 15 seconds and then plug back in. If problem persists, contact an authorized service representative (see Calling For Service later in this manual).</i>
C102: FILL MODE STOP PRESSED	<i>STOP button was pressed during cycle.</i>	<i>Push STOP button to restart.</i>
C103 through C106	<i>STOP button was pressed during cycle.</i>	<i>Push STOP button to restart. Wait briefly (up to one minute) while chamber pressure / temperature dissipates. Then press STOP button to return to Select Cycle mode where a new cycle may be initiated.</i>
C232: FILL MODE WATER LOW	<i>Water level in reservoir is too low.</i>	<i>Push STOP button to restart. Refill water reservoir with distilled or demineralized water. Wait briefly (up to one minute). Then press STOP button to return to Select Cycle mode where a new cycle may be initiated</i>
C326: DOOR MODE DOOR CLOSED	<i>Operator closed door during drying cycle.</i>	<i>Open sterilizer door.</i>

Operator
Maintenance

Message Guide - Continued

Message	Possible Cause	Solution
C382: FILL MODE DOOR OPEN	Sterilizer detects that door is open.	Close the sterilizer door.
C383	—	Push STOP button to restart. Wait briefly (up to one minute) while chamber pressure / temperature dissipates. Then press STOP button to return to Select Cycle mode where a new cycle may be initiated.
C384	—	Unplug unit power cord for 15 seconds and then plug back in. If problem persists, contact an authorized service representative (see Calling For Service later in this manual).
C431 through C467	—	Push STOP button to restart.
C470 through C633	—	Unplug unit power cord for 15 seconds and then plug back in. If problem persists, contact an authorized service representative (see Calling For Service later in this manual).
C642 through C647	—	Push STOP button to restart. Wait briefly (up to one minute) while chamber pressure / temperature dissipates. Then press STOP button to return to Select Cycle mode where a new cycle may be initiated.
C660 through C987	—	Unplug unit power cord for 15 seconds and then plug back in. If problem persists, contact an authorized service representative (see Calling For Service later in this manual).

Calling For
Service

CALLING FOR SERVICE

If you are having a problem or have a question, refer to the inside front cover of this manual and call your dealer. Make sure that you have the information that is highlighted on the inside front cover of this manual available. If you can't resolve your question or problem with your dealer, call the following number:

1-800-Midmark (1-800-643-6275) or 937-526-3662
8:00 a.m. until 5:00 p.m. (Eastern Standard Time in the U.S.)
Monday thru Friday, except for standard U.S. holidays.

SPECIFICATIONS

Physical Dimensions:

Overall Length	20.7 in. (52.6 cm)
Overall Width.....	15.3 in. (38.9 cm)
Overall Height	15.9 in. (40.4 cm)
Counter Area.....	15.3 in. x 20.7 in. (38.9 cm x 52.6 cm)
Chamber	4.5 in. x 9 in. x 12 in. (11.4 x 22.9 x 30.5)
Standard Trays	7 in. x 11 in. x 0.75 in. (17.8 cm x 27.9 cm x 1.9 cm)

Weight:

Empty Reservoir.....	89 lbs (40.4 Kgs)
With Shipping Carton	97 lbs (44.0 Kgs)
Water Reservoir Capacity	Approximately 1.5 Gallons (9.5 liters) to Full Mark usable volume is 1.0 gallons (3.8 liters)

Electrical Requirements:

NOTE: A separate (dedicated) circuit is required for this sterilizer. The sterilizer should not be connected into an electrical circuit with other appliances or equipment unless the circuit is rated for the additional load.

115 VAC, 50/60 Hz Model	15 AMP Circuit, Single Phase
230 VAC, 50/60 Hz Model	10 AMP Circuit, Single Phase

Fuse Rating (115 VAC Units)	Fast acting, 15A, 600V, 13/32 x 1-1/2 in.
Fuse Rating (230 VAC Units)	Fast acting, 8A, 600V, 13/32 x 1-1/2 in.

Chamber Pressure at

270°F (132°C)	27.1 psi. (186.2 kPa)
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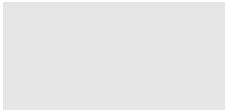
Safety Valve Setting	40 psi. (275.8 kPa)
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Certifications	AAMI ST55 ASME Boiler & Pressure Vessel Code UL3101-1
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Operator
Maintenance

Calling For
Service

Specifications



LIMITED WARRANTY

SCOPE OF WARRANTY

Midmark Corporation ("Midmark") warrants to the original purchaser its new Alternate Care products and components (except for components not warranted under "Exclusions") manufactured by Midmark to be free from defects in material and workmanship under normal use and service. Midmark's obligation under this warranty is limited to the repair or replacement, at Midmark's option, of the parts or the products the defects of which are reported to Midmark within the applicable warranty period and which, upon examination by Midmark, prove to be defective.

APPLICABLE WARRANTY PERIOD

The applicable warranty period, measured from the date of delivery to the original user, shall be one (1) year for all warranted products and components.

EXCLUSIONS

This warranty does not cover and Midmark shall not be liable for the following: (1) repairs and replacements because of misuse, abuse, negligence, alteration, accident, freight damage, or tampering; (2) products which are not installed, used, and properly cleaned as required in the Midmark "Installation" and or "Installation / Operation Manual" for this applicable product. (3) products considered to be of a consumable nature; (4) accessories or parts not manufactured by Midmark; (5) charges by anyone for adjustments, repairs, replacement parts, installation, or other work performed upon or in connection with such products which is not expressly authorized in writing in advance by Midmark.

EXCLUSIVE REMEDY

Midmark's only obligation under this warranty is the repair or replacement of defective parts. Midmark shall not be liable for any direct, special, indirect, incidental, exemplary, or consequential damages or delay, including, but not limited to, damages for loss of profits or loss of use.

NO AUTHORIZATION

No person or firm is authorized to create for Midmark any other obligation or liability in connection with the products.

THIS WARRANTY IS MIDMARK'S ONLY WARRANTY AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED. MIDMARK MAKES NO IMPLIED WARRANTIES OF ANY KIND INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACEMENT OF DEFECTIVE PARTS.

SF-1487 REV. A1

PRINTER INSTALLATION AND OPERATION

The printer is an optional add-on that some units may have. The printer may also be purchased as an accessory at a later date and installed.

Installing the Printer



WARNING

Disconnect all electrical power to the unit before removing any of the unit's covers/ shrouds or making any repairs to prevent the possibility of electrical shock. Failure to comply with these instructions could result in serious personal injury or death.

1. Unplug sterilizer power cord from electrical outlet.



EQUIPMENT ALERT

Use care when removing printer cover plate with flat bladed screwdriver not to mar top surface of top cover.

-

Figure 1

MA464701i

6. Route loose end of PCB printer harness (1, Figure 2) through slot (A) in printer cavity (4) of top cover.
7. Plug PCB printer harness (1) into printer terminal (2) of PC Board.
8. Position printer assembly (3) in printer cavity (4).

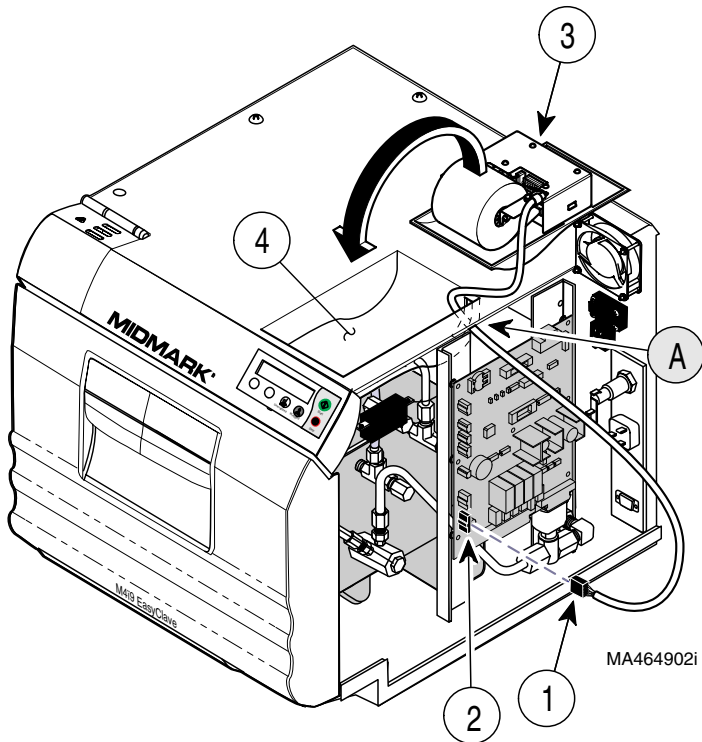


Figure 2

9. Insert three tabs (A, Figure 3) of right hand side panel (1) into three slots (B) of base (2).
10. Raise top edge of right hand side panel (1) into position under top cover (3) and secure using two screws (4) and one screw (5). Make sure back lip of right hand side panel is on outside of back panel; not on inside.
11. Plug sterilizer power cord into electrical outlet.
12. Insert a paper roll if necessary (see Inserting Paper Roll later in this manual).

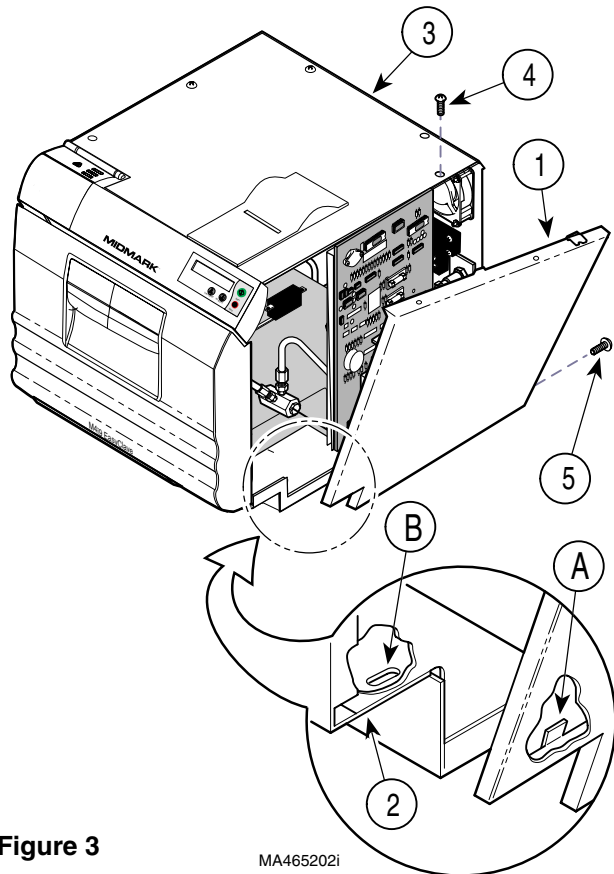


Figure 3

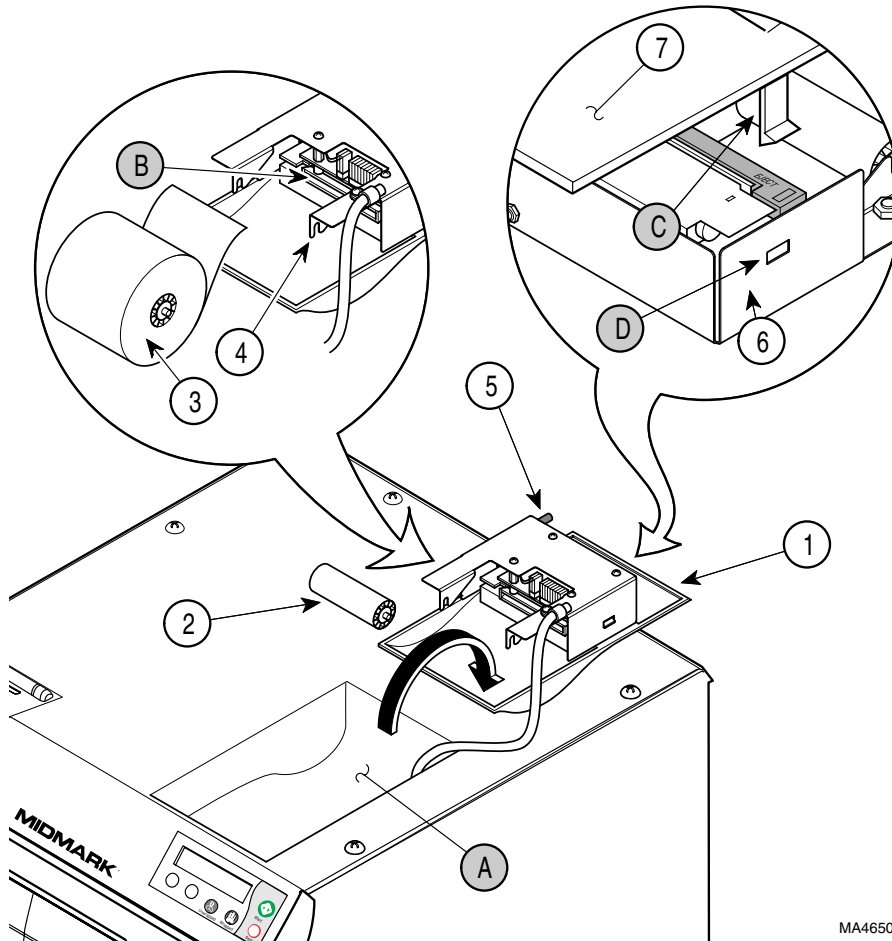
MA465202i

Operating the Printer

When the sterilizer is plugged in, the printer is automatically powered up and initialized; no user intervention / setup is required.

Inserting the Paper Roll

1. Remove the printer assembly (1) from the printer cavity (A) and turn it onto its back.
2. Remove paper spindle (2) from used paper roll and insert it in new paper roll (3).



MA465002i

3. Unroll 2 to 3 in.(5 to 7.5 cm) of paper (3).
4. Cut a straight edge on the paper (3) if it is torn or jagged; this will facilitate the entry of paper into the printer.

5. Slide the paper (3) into the slot (B) on the back of the printer; it will slide in 1/4 in. (6.4 mm) before it stops.

NOTE

If paper (3) does not feed out of top of printer by itself, remove printer assembly (6) from printer housing (7) by pulling two locking tabs (C) from locking slots (D). Feed paper through paper slot in printer housing (7) by hand and then re-attach printer assembly (6) to printer housing (7) by inserting two locking tabs (C) into locking slots (D).

6. While holding the paper (3) in place, press the PAPER FEED button (5) and hold. The printer will activate and a rubber roller will pull the paper into the printer compartment. Continue to hold the PAPER FEED button down until the paper emerges from the top of the printer mechanism. Then, when 1 in. (2.5 cm) of paper has emerged from the top of the printer, release the PAPER FEED button.
7. Pull the paper (3) through the printer until 2 to 3 in. (5 to 7.5 cm) of paper is exposed.
8. Install the paper roll (3) by inserting the ends of the paper spindle (2) in slots of spindle holders (4).
9. Turn the paper roll so as to take up the slack in the paper feeding to the printer. Make sure the roll of paper turns freely. If it does not turn freely, the paper will jam and possibly damage the printer mechanism.
10. Install the printer assembly (1) back into the printer cavity (A).

About the Cartridge Ribbon

The printer takes a cartridge ribbon. If the printed material is difficult to read and you suspect a dried out ribbon is the cause of the problem, advance to a properly inked portion of the ribbon by pressing the PAPER FEED button for three seconds. When printing becomes faint or difficult to see and pressing the PAPER FEED button for three seconds does not correct the problem, you should replace the cartridge (see Installing a New Cartridge Ribbon later in this manual).

Installing a New Cartridge Ribbon

1. Unplug the sterilizer power cord from electrical outlet.
2. Remove the printer assembly (1) from the printer cavity (A).
3. Slightly bend sides of housing (2) outward until housing can be pulled off of locking tabs (B). Remove printer housing (3) from printer assembly (4).

4. Push down on the right side (C) of the ribbon cartridge (5) (marked PUSH) and remove the old ribbon cartridge.
5. Install the new ribbon cartridge (5). Be sure the ribbon is inserted in front of the paper and the ribbon is flat against the paper. Press the ribbon cartridge (5) downward until it snaps into place.
6. Turn the knob (6) on the ribbon cartridge (marked by an arrow) clockwise to stretch the ribbon so it is tight.
7. Re-attach printer assembly (4) to printer housing (3) by inserting two locking tabs (B) into locking slots (D).
8. Position printer assembly (1) in printer cavity (A).
9. Plug sterilizer power cord into electrical outlet.

Removing the Paper Roll



EQUIPMENT ALERT

Be sure to pull the paper out of the top of the printer. Pulling the paper out of the back of the printer will damage the printer mechanism.

Before removing the paper roll, advance the paper about 1 in. (2.5 cm) by pressing down and holding the PAPER FEED button. Lift the paper roll away from the printer housing, and with a scissors, cut the paper roll feeding to the printer. Try to make the cut as straight as possible to facilitate the next reloading of the paper. Now, pull the remaining paper through the printer mechanism.

Power Up Message

When the printer successfully initializes after the sterilizer is powered up, it prints the word READY to assure the operator that its built in microprocessor is working properly and the sterilization cycles will be recorded by the printer.

Printer Tape Description

The printer will print the following information for each program cycle:

Cycle Type

Set Temperature

Set Time

Run Number

Date: Lines are printed for the month, day, and year so that the date can be recorded on the printer tape.

The printer will print the chamber temperature, the chamber pressure, and the time elapsed in two (2) minute increments during the heat up phase.

During the actual Sterilization Phase of the program cycle, the printer will record the chamber temperature, chamber pressure, and the time elapsed for each 1/2 minute of the program cycle.

When the sterilizer has completed the Sterilization Phase of the program cycle, the printer will print the word VENTING CHAMBER to show that the steam pressure is being exhausted from the chamber.

When the sterilizer has completed the Drying Phase of the program cycle, the word COMPLETE will be printed to show that the sterilizer has completed the sterilization program cycle.

The figure below shows an example of a typical printout of a program cycle:

Typical Printout of a Program Cycle

```
BEGIN

UNWRAPPED
270 degF 3:30 MINUTES

MM - DD - YYYY
-- - - - -
TOTAL CYCLES  123

HEATING-UNWRAPPED

MM:SS   degF   PSI
0:00    224    0.0
2:00    236    10.8

STERILIZING
3:30    271    28.2
3:00    273    29.1
2:30    273    29.0

MIN TEMP      271
MAX TEMP      274
MIN PRESS     28.2
MAX PRESS     29.5

VENTING CHAMBER

DRYING
20:00
```

Typical Printout of a Program Cycle - Continued

```
15:00
10:00
5:00
0:00

TOTAL PROCESS TIME
0:20:56
COMPLETE
```

NOTES:

NOTES:

DECLARATION OF CONFORMITY



MIDMARK CORPORATION

Midmark Corporation declares that pressure vessels manufactured by Midmark Corporation and marked with the ASME "U" stamp comply to the applicable requirements of the American Society of Mechanical Engineers Boiler and Pressure Vessel Code, Section VIII, Division 1.

ASME CERTIFICATE OF AUTHORIZATION NUMBER: 25,127

Quality Assurance / Regulatory Affairs Manager

Gene Harshbarger
Midmark Corporation
60 Vista Drive PO Box 286
Versailles, Ohio 45380 U.S.A.
September 21, 1999

MIDMARK[®]

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